UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRANCIS NEARY, individually and on behalf of all others similarly situated, Plaintiff, v. SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; CHATTEM, INC.; and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendants.	Civil Action No. _____ **CLASS ACTION COMPLAINT** Class Action Demand for Jury Trial

Plaintiff Francis Neary, on behalf of himself and all others similarly situated, in his action against Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants"), and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") alleges the following based on personal knowledge, the investigation of counsel, and information and belief.

INTRODUCTION

1. This case is brought as a class action lawsuit regarding Defendants' manufacturing, distribution, and sale of ranitidine-based over-the-counter medications under the brand name Zantac that contain dangerously high levels of N-nitrosodimethylamine ("NDMA"), a carcinogen.

FACTS COMMON TO THE CLAIMS

2. Zantac is used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.[1] Zantac was first sold in the United States in

[1] *Ranitidine hydrochloride – Drug Summary*, PRESCRIBER'S DIGITAL REFERENCE (last visited Nov. 18, 2019), https://www.pdr.net/drug-summary/Zantac-150-and-300-Tabletsranitidine-hydrochloride-241.3325.

1983; three years later, it became the first drug to total $1 billion in sales.[2]

3. Zantac is a widely used over-the-counter medication and one of the most popular brands of antacid[3] in the United States. Sales of Zantac 150 (the over-the-counter tablets containing a 150 mg dose) total $128.9 million annually.[4] Over-the-counter Zantac also is sold in the form of tablets containing a 75 mg dose (Zantac 75).

4. Zantac's unprecedented sales were possible only because of a deception perpetrated by the drug's manufacturers on consumers who have purchased Zantac since it hit the market in 1983. Sanofi and Boehringer are only the most recent manufacturers to carry out this deception.

5. Sanofi has owned the U.S. rights to over-the-counter Zantac since about January 2017, and has manufactured and distributed the drug during that period. Previously, Defendant Boehringer owned the U.S. rights to Zantac and manufactured and distributed the drug from about October 2006 to January 2017.

6. Neither Sanofi nor Boehringer ever disclosed to consumers that the drug has a critical defect: when ingested, Zantac produces in the human body high quantities of NDMA, a chemical that the World Health Organization has described as "clearly carcinogenic."[5] The dangers of NDMA have been publicly known for over 40 years.[6] NDMA itself belongs to a family of chemicals called

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[2] Richard Wright, M.D., *How Zantac Became the Best-Selling Drug in History*, 16(4) J. HEALTHCARE MARKETING 24 (Winter 1996).

[3] Zantac is not technically an antacid because it "works by reducing the amount of acid [the] stomach makes," whereas antacids "neutralize the acid that your stomach has already made." *See Ranitidine, Oral Tablet*, HEALTHLINE (last visited Nov. 18, 2019), https://www.healthline.com/health/ranitidine-oral-tablet. Nonetheless, this Complaint sometimes refers to Zantac as an antacid because this is often how the drug is referred to colloquially. *See, e.g.*, *Leading antacid tablet brands in the United States in 2018, based on sales*, STATISTA (last visited Nov.18, 2019), https://www.statista.com/statistics/194544/leading-us-antacid-tabletbrands-in-2013-based-on-sales.

[4] *Leading antacid tablet brands in the United States in 2018*, *supra* n. 3.

[5] R.G. Liteplo, *et al*., *Concise International Chemical Assessment Document 38:* N-*Nitrosodimethylamine*, WORLD HEALTH ORGANIZATION (2002), *available at* https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

[6] *See, e.g*., Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979) ("As one of a family of carcinogens called nitrosamines, NDMA has caused cancer in nearly every laboratory animal tested so far.").

N-nitrosamines, which the U.S. Environmental Protection Agency refers to as "potent carcinogens."

7. On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine medications, including Zantac.[7] The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of ranitidine."[8]

8. Several pharmaceutical manufacturers have issued recalls or halted the sale of their ranitidine medications. Pharmacies such as Walgreens, Rite Aid, and CVS have also ceased selling ranitidine medications.

9. On October 18, 2019, Sanofi issued a voluntary recall of Zantac "due to inconsistencies in preliminary test results" of the active ingredient in Zantac.[9] Despite this, Sanofi's recall notice on the Zantac website continues to direct consumers to a separate, pre-recall notice by Sanofi touting the safety of Zantac. Specifically, the notice states: "The longstanding science supports the safety of Zantac, which has been available over-the-counter for over two decades."[10]

10. The representations concerning Zantac are false. Zantac contains the carcinogenic impurity NDMA, a chemical that the World Health Organization has described as "clearly carcinogenic."

11. The Medicines and Healthcare Products Regulatory Agency (MHRA) of the United

[7] Food & Drug Admin., Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[8] Food & Drug Admin., 10/2/19: UPDATE – FDA Provides Update on Testing of Ranitidine for NDMA Impurities (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[9] Jen Christensen, *Sanofi Recalls Popular Heartburn Medication Zantac OTC*, CNN, Oct. 18, 2019, https://www.cnn.com/2019/10/18/health/zantac-otc-recall/index.html (last visited Nov. 18, 2019).

[10] ZANTAC STATEMENT, https://www.zantacotc.com (last visited Nov. 14, 2019) (click "Read More" on "A Message From Sanofi").

Kingdom also issued an alert regarding Zantac, noting recalls issued by companies are "a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with the impurity NDMA."[11] "The MHRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue."[12]

12. In the case of Zantac and other ranitidine medications, the cause of the NDMA contamination is still being investigated by the FDA and other regulatory agencies. However, the Health Products Regulatory Authority of Ireland, in issuing a recall of Zantac, has stated, "The reason for the recall is that a nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India."[13]

13. The FDA recently announced a permissible intake limit of 96 ng of NDMA per day.[14] But even this limit may be too high: A public health statement issued 30 years ago by the Agency for Toxic Substances and Disease Registry warned of the dangers posed by NDMA, noting among other things that "high level short-term and *low level long-term exposures* [to NDMA] caused non-cancerous liver damage and/or cancer in animals [and] also usually resulted in internal bleeding and death."[15]

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[11] Medicine and Healthcare Regulatory Agency, Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls all Unexpired Stock (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[12] *Id.*

[13] Health Products Regulatory Authority, Precautionary Pharmacy and Retail Level Recall of Several Batches of a Number of Ranitidine Medicines in Ireland (Sept. 23, 2019), https://www.hpra.ie/homepage/medicines/safety-notices/item?t=/precautionary-pharmacy-and-retail-level-recall-of-several-batches-of-a-number-of-ranitidine-medicines-in-ireland&id=d26b0c26-9782-6eee-9b55-ff00008c97d0.

[14] FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan), FDA (last updated Aug. 28, 2019) (setting "interim limits for NDMA" and other nitrosamines at 96 ng/day for angiotensin II receptor blockers).

[15] Agency for Toxic Substances & Disease Registry, PUBLIC HEALTH STATEMENT FOR N-NITROSODIMETHYLAMINE 2 (Dec. 1989) (emphasis added), available at https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=173. The

14. The FDA has established a "permissible daily intake limit for…NDMA of 96 [nanograms]." But Zantac has an NDMA content of between 2.5-2.8 million nanograms per tablet, according to testing by Valisure, an FDA-registered online pharmacy.

15. When the news broke on September 13, 2019 that Zantac exposed users to NDMA, "[g]lobal health regulators sounded a coordinated alarm."[16]

16. Plaintiff has purchased the over-the-counter version of the drug Zantac in New York during the relevant period, January 1, 2010 to the present.

17. Plaintiff and the Class were injured by the full purchase price of their Zantac medications. These medications are worthless, as they contain harmful levels of NDMA. As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendants' conduct.

18. Had Plaintiff and Class members known that taking Zantac would expose them to high levels of the carcinogen NDMA, they would not have purchased the drug.

19. Defendants' failure to disclose this material information to Plaintiff and Class members violates the laws of New York as well as laws in the United States.

20. Plaintiff brings this action on behalf of the Class for equitable relief and to recover damages and restitution for: (i) violation of New York's General Business Law § 349; (ii) breach of the express warranty; (iii) breach of the implied warranty; (iv) fraudulent concealment; (v) violation of New York's General Business Law § 350; and (vi) fraud.

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public health statement also notes that "[s]hort-term or long-term exposure of animals to water or food containing NDMA is also associated with serious effects, such as liver disease and death, at levels ranging from 5 to 50 ppm [parts per million] in water and 5 to 100 ppm in food."

[16] Anna Edney & John Lauerman, *Carcinogen in Zantac and its generics triggers probes by FDA, EU*, THE HAMILTON SPECTATOR (Sept. 13, 2019), https://www.thespec.com/newsstory/9595764-carcinogen-in-zantac-and-its-generics-triggers-probes-by-fda-eu/.

PARTIES

Plaintiff

21. Plaintiff Francis Neary ("Plaintiff") is a citizen of New York who resides in Melville, New York. During all relevant time periods, Plaintiff purchased and consumed Zantac manufactured by Defendants. Plaintiff took the drug every evening to treat acid reflux at times during the relevant period. During the time that he has taken Zantac, Plaintiff has generally purchased Zantac in the form of 150 mg tablets at CVS and Rite Aid Stores in New York. Plaintiff spent in excess of $500 on Zantac during the relevant period.

22. When purchasing Zantac from Defendants, Plaintiff reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured, free from defects, and safe for their intended use. Plaintiff relied on these representations and warranties in deciding to purchase Zantac from Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased Zantac from Defendants if he had known that they were not, in fact, properly manufactured and free from defects. Plaintiff also understood that each purchase involved a direct transaction between himself and Sanofi because his medication came with packaging and other materials prepared by Defendants, including representations and warranties that his medications were properly manufactured and free from defects.

23. If Plaintiff had known that taking Zantac would expose him to unsafe quantities of NDMA, he would not have purchased or used the drug.

Defendants

24. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly

owned subsidiary of the French company Sanofi.

25. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

26. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business at 1715 West 38th Street, Chattanooga, Tennessee 37409, and is a wholly owned subsidiary of the French company Sanofi.

27. Defendants Sanofi-Aventis U.S. LLC; Sanofi US Services Inc.; and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants") controlled the U.S. rights to over-the-counter Zantac from about January 2017 to the present and manufactured and distributed the drug in the United States during that period.

28. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to over-the-counter Zantac from about October 2006 to January 2017 and manufactured and distributed the drug in the United States during that period.

JURISDICTION AND VENUE

29. This Court has jurisdiction under 28 U.S.C. § 1332(d), which provides federal district courts with original jurisdiction over any civil action in which the matter in controversy exceeds the sum or value of $5 million, exclusive of interests and costs, and is a class action in which any member of a class of plaintiffs is a citizen of a state different from any defendant.

30. The Court has personal jurisdiction over each Defendant because each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in this District.

Defendants' unlawful conduct has injured persons residing in, located in, or doing business throughout this District.

31. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) because each Defendant transacts business in, is found in, and/or has agents in this district, and because a substantial part of the events giving rise to this action occurred within this district.

DEFENDANTS' FAILED TO DISCLOSE TO CONSUMERS THAT ZANTAC EXPOSED CONSUMERS TO HIGH LEVELS OF NDMA, A KNOWN CARCINOGEN, DESPITE SCIENTIFIC STUDIES WHICH ALERTED DEFENDANTS TO THIS FACT

32. During the time that Defendants manufactured and sold over-the-counter Zantac in the United States, the weight of scientific evidence showed that Zantac exposed users to unsafe levels of NDMA. Neither Sanofi nor Boehringer ever disclosed this risk to consumers on the drug's label—or through any other means—nor did Defendants report these risks to the FDA.

33. Although there were some scientific articles linking ranitidine—the active ingredient in Zantac—to NDMA in the first few years after the drug's U.S. launch, those articles tended to minimize the danger that ranitidine posed to consumers.[17]

34. During the time that Defendants were manufacturing and selling over-the-counter Zantac in the United States, however, the scientific evidence linking Zantac and NDMA was mounting and should not have been ignored by Defendants.

35. For example, a 2011 scientific study found that, out of eight pharmaceuticals that were observed, "ranitidine showed the strongest potential to form N-nitrosodimethylamine

[17] *See, e.g.*, Silvio De Flora, *et al*., *Genotoxicity of nitrosated ranitidine*, 4(3) CARCINOGENESIS 255, 260 (1983) (stating that "the potential risk linked with [ranitidine] use is probably negligible"); J. Meyrick Thomas, *et al*., *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 28 GUT 726, 737 (1987) ("The most important findings of this study are that . . . N-nitroso compound concentration did not increase during prolonged maintenance treatment with ranitidine . . . ."); Jun Matsuda, *Nitrosamines in gastric juice of patients with gastric ulcer before and during treatment with histamine H2-receptor antagonists*, 25(2) GASTROENTEROLOGIA JAPONICA 162, 168 (1990) ("The amounts of NDMA and NDEA found in human gastric juice even when patients were given H2-blockers seemed too small to produce carcinogenesis in a short time in man.").

(NDMA)" when present in drinking water during chloramine disinfection.[18] The same study noted that "[r]anitidine gave a much higher yield of NDMA in the present study than reported in [prior] literature."[19] Another 2011 scientific article that examined ranitidine in the water supply also found that the drug was "an important NDMA precursor."[20]

36. A 2014 scientific article that examined the formation mechanisms of NDMA acknowledged the consensus about the dangers posed by ranitidine, observing that ranitidine and two other pharmaceuticals had "recently caused much concern because they are potent NDMA precursors."[21]

37. A 2018 scientific review "summariz[ing] major findings over the last decade related to N-Nitrosodimethylamine (NDMA)"[22] again pointed out that ranitidine had a high rate of NDMA formation "upon chloramination."[23]

38. Despite the undeniable scientific evidence linking ranitidine to the production of high levels of NDMA, Defendants did not disclose this link to consumers on Zantac's label or through any other means.

39. Defendants concealed the Zantac–NDMA link from consumers in part by not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit

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[18] Ruqiao Shen & Susan A. Andrews, *Demonstration of 20 pharmaceuticals and personal care products (PPCPs) as nitrosamine precursors during chloramine disinfection*, 45 WATER RESEARCH 944 (Oct. 13, 2010). "Chloramination is the process of adding chloramine to drinking water to disinfect it and kill germs. Chloramination is sometimes used as an alternative to chlorination." *Disinfection with Chloramine*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Jan. 20, 2015), https://www.cdc.gov/healthywater/drinking/public/chloramine- disinfection.html.

[19] Shen & Andrews, *supra* n. 18, at 948.

[20] Julien Le Roux, *et al*., *Chloramination of nitrogenous contaminants (pharmaceuticals and pesticides): NDMA and halogenated DBPs formation*, 45 WATER RESEARCH 3164, 3165 (Mar. 26, 2011).

[21] Yong Dong Liu, *et al*., *Formation Mechanism of NDMA from Ranitidine, Trimethylamine, and Other Tertiary Amines during Chloramination: A Computational Study*, 48 ENVTL. SCI. & TECHNOLOGY 8653, 8660 (June 26, 2014).

[22] *See, e.g.*, Massimiliano Sgroi, *et al*., *N-Nitrosodimethylamine (NDMA) and its precursors in water and wastewater: A review of formation and removal*, 191 CHEMOSPHERE 685 (Oct. 15, 2017).

[23] *Id.* n. 22, at 698.

citizen petitions) to bring new information about an approved drug like Zantac to the agency's attention.

40. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety:

> The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.[24]

41. The manufacturer's annual report also must contain "[c]opies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product."[25]

42. Defendants simply ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Zantac.

43. Defendants never provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA.

CLASS ACTION ALLEGATIONS

44. Plaintiff brings this action under Federal Rule of Civil Procedure 23(a) and (b)(3), on behalf of himself and all others similarly situated.

45. Plaintiff seeks to represent the following Classes:

> **The Nationwide Class:** All persons who purchased over-the-counter Zantac in the United States for personal, family, or household use during the Class Period.

[24] 21 C.F.R. § 314.81(b)(2).

[25] 21 C.F.R. § 314.81(b)(2)(v).

The New York Subclass: All persons who purchased over-the-counter Zantac in New York for personal, family, or household use during the Class Period.

46. For purposes of this action, the Class Period is defined as the period from January 1, 2010 through the present.

47. Excluded from the Class are each Defendant and any entity in which a Defendant has a controlling interest, as well as any Defendant's legal representatives, officers, directors, assignees, and successors.

48. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. During the Class Period, over-the-counter Zantac was one of the best-selling antacid medications in the United States. Hundreds of thousands—if not millions—of persons purchased the drug. Class members are readily identifiable from information and records in the possession of Defendants and third-party pharmacies such as CVS, Walgreens, Walmart, and Rite Aid.

49. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all Class members were damaged by the same wrongful conduct of Defendants: As a result of Defendants' failing to disclose that Zantac exposed users to unsafe levels of the carcinogen NDMA, Plaintiff and Class members were misled into purchasing Zantac—a drug they otherwise would not have purchased. There are numerous Zantac substitutes; in addition to other H2 blockers such as Pepcid-AC and Tagamet-HB, there are also proton pump inhibitors—for example, Dexilant, Nexium, Prevacid, Protonix, AcipHex, and Prilosec—which "block the enzyme in the stomach wall that makes acid."[26]

50. Plaintiff will fairly and adequately protect and represent the interests of the Class.

[26] *How Acid Reducers Can Help Treat Heartburn*, WEBMD (June 10, 2017), https://www.webmd.com/heartburn-gerd/h2-blockers-how-acid-reducers-can-help-treat-gerd- symptoms.

The interests of Plaintiff are coincident with, and not antagonistic to, those of the other members of the Class.

51. Plaintiff's lead counsel are experienced in the prosecution of class-action litigation and have particular experience with class-action litigation involving pharmaceutical products.

52. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful actions.

53. Questions of law and fact common to the Class include, but are not limited to:

a. Whether the Zantac sold by Defendants exposed Plaintiff and Class members to unsafe levels of the carcinogen NDMA;

b. Whether Defendants knew or had reason to know that Zantac exposes users to unsafe quantities of NDMA;

c. Whether Defendants acted to conceal from consumers that Zantac exposes users to unsafe quantities of NDMA;

d. Whether Defendants' conduct was knowing or willful;

e. Whether Defendants notified the FDA that Zantac exposes users to unsafe quantities of NDMA;

f. Whether Defendants attempted to gain approval from the FDA to change Zantac's label to add a warning that the drug exposes users to unsafe quantities of NDMA;

g. Whether Defendants acted to conceal from the FDA the link between Zantac and NDMA;

h. Whether Defendants' failure to disclose on Zantac's label (or elsewhere) that the drug produces high levels of the carcinogen NDMA was unfair, deceptive, fraudulent, or unconscionable;

i. Whether Defendants are liable to Plaintiff and Class members for damages under state consumer-protection statutes;

j. When Defendants manufactured and sold Zantac in the United States;

k. Whether an injunction should be issued requiring Sanofi Defendants to disclose on Zantac labels that the drug exposes users to unsafe levels of NDMA; and

l. Whether Plaintiff and Class members are entitled to attorneys' fees, prejudgment interest, and costs, and if so, in what amount.

54. Plaintiff and Class members have all suffered harm and damages as a result of Defendants' unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of this controversy under Rule 23(b)(3). Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism—including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually—substantially outweigh potential difficulties in management of this class action. Absent a class action, most members of the Class would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law. The class treatment of common questions of law and fact also is superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants, and promotes consistency and efficiency of adjudication. Additionally, Defendants have acted and failed to act on grounds generally applicable to Plaintiff and the Class and require court imposition of uniform relief to ensure compatible standards of conduct toward the Class, thereby making appropriate equitable relief to the Class as a whole within the meaning of Rules 23(b)(1) and (b)(2).

55. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

TOLLING OF THE STATUTE OF LIMITATIONS AND ESTOPPEL

A. Discovery Rule Tolling

56. Within the period of any applicable statutes of limitation, Plaintiff and members of the proposed Class could not have discovered through the exercise of reasonable diligence that Defendants were not disclosing the high levels of the carcinogen NDMA produced by Zantac.

57. Plaintiff and the other Class members did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants did not disclose the high levels of NDMA produced by Zantac. The information linking Zantac to NDMA was contained exclusively in articles that were published in scientific journals. Plaintiff and Class members did not have access to these scientific articles because they were behind a paywall. And even had the articles been more widely available, the significance of these highly technical articles would not have been apparent to Plaintiff or Class members.

58. Plaintiff and Class members could not have reasonably discovered the true extent of Defendants' deception with regard to Zantac's safety until the online pharmacy Valisure filed its citizen petition disclosing the extremely high levels of NDMA produced by Zantac.

59. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule.

B. Fraudulent Concealment Tolling

60. All applicable statutes of limitation have also been tolled by Defendants' fraudulent concealment throughout the period relevant to this action of Zantac's producing high levels of the carcinogen NDMA.

61. Instead of disclosing to consumers the link between Zantac and the carcinogen NDMA, Defendants continued to manufacture and sell Zantac without disclosing this information

on the drug's label or elsewhere.

C. Estoppel

62. Defendants were under a continuous duty to disclose to Plaintiff and the other Class members the risk of NDMA exposure associated with Zantac.

63. Defendants knowingly, affirmatively, and actively concealed or recklessly disregarded the true risks of NDMA exposure associated with Zantac and never updated the drug's label to disclose this risk.

64. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

CLAIMS FOR RELIEF

COUNT I
Violation of New York Consumer Protection Law
(N.Y. Gen. Bus. Law § 349)
(On Behalf of the New York Subclass)

65. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

66. This claim is brought by Plaintiff against all Defendants on behalf of himself and the New York Subclass.

67. New York's General Business Law section 349 declares unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in the state of New York.

68. At all relevant times, Defendants conducted business, trade and commerce in New York and across the United States.

69. As described in this Complaint, Defendants conduct constitutes "deceptive" acts or practices in violation of GBL § 349.

70. Defendants' practices violated GBL § 349 for, among other things, the following reasons:

a. Defendants concealed from Plaintiff and Class members the material fact that Zantac was defective, and as such, was not of merchantable quality.

b. Defendants failed to disclose material information discussed above regarding the relationship between Zantac and NDMA.

71. Defendants consciously omitted to disclose material facts to Plaintiff and the Subclass members regarding the defects in Zantac.

72. Defendants' deceptive conduct described herein includes the omission and concealment of material facts concerning the defects in Zantac.

73. Defendants intended that Plaintiff and Subclass members would rely on their omissions and misrepresentations so that Plaintiff and Subclass members would purchase Zantac.

74. Had Defendants disclosed all material information regarding the defects in Zantac to Plaintiff and Subclass members, they would not have purchased Zantac.

75. The foregoing acts, omissions, and practices proximately caused Plaintiff and Subclass members to suffer an ascertainable loss in the form of, among other things, the money they paid for Zantac.

76. Plaintiff and Subclass members are entitled to enjoin Defendants' deceptive practices, and to recover their actual damages or fifty dollars, whichever is greater, including treble damages and reasonable attorney fees.

77. Defendants knew that the Zantac they were manufacturing and distributing was defective and was not suitable for its intended use. Defendants had notice of this fact through numerous scientific articles showing that Zantac produces NDMA. Defendants nonetheless failed to warn Plaintiff and Subclass members about this defect despite having a duty to do so.

78. By failing to disclose and by actively concealing the defects in Zantac, which they marketed as safe, Defendants engaged in deceptive business practices in violation of GBL § 349.

79. In the course of Defendants' business, they willfully failed to disclose and actively concealed the dangerous risk posed by the defects in Zantac.

80. Defendants' deceptive acts or practices were likely to and did in fact deceive reasonable consumers, including Plaintiff and Subclass members, about the true safety of Zantac.

81. Defendants intentionally and knowingly misrepresented material facts regarding Zantac with the intent to mislead Plaintiff and Subclass members.

82. Defendants knew or should have known that their conduct violated GBL § 349.

83. As alleged above, Defendants made material statements about the safety of Zantac that were either false or misleading.

84. Defendants had a duty to disclose to Plaintiff and Subclass members the truth about the safety of Zantac.

85. Had Plaintiff and Subclass members been aware of the NDMA exposure caused by Zantac, they would not have purchased Zantac.

86. Defendants' concealment of the defects in Zantac was material to Plaintiff and Subclass members.

87. Plaintiff and Subclass members suffered ascertainable loss caused by Defendants' misrepresentations and concealment of and failure to disclose the defects in Zantac.

88. As a direct and proximate result of Defendants' violations of GBL § 349, Plaintiff and Subclass members have suffered injury-in-fact and actual damages, as alleged above.

89. Because Defendants' deceptive conduct caused injury to Plaintiff and Subclass members, Plaintiff and Subclass members seek a refund for their purchases of Zantac, together

with appropriate penalties, including treble damages, reasonable attorneys' fees, costs, and any other legal or equitable relief that the Court deems just and appropriate.

COUNT II
Breach of Express Warranties
(On Behalf of The Nationwide Class and the New York Subclass)

90. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

91. This claim is brought against all Defendants by Plaintiff on behalf of himself, the Nationwide Class, and the New York Subclass.

92. Plaintiff, and each member of the Class and New York Subclass, formed a contract with Defendants at the time Plaintiff and the other Class and New York Subclass members purchased the defective Zantac. The terms of the contract include the promises and affirmations of fact made by Defendants on Zantac's packaging and through marketing and advertising, including that the product would contain only what was stated on the label, and not harmful impurities such as NDMA. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

93. Plaintiff relied on the express warranty that his Zantac was safe and would not contain unsafe levels of NDMA. This express warranty further formed the basis of the bargain, and is part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

94. Defendants purport, through their advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on the label, and not harmful impurities such as NDMA.

95. Plaintiff and the Class and New York Subclass performed all conditions precedent to Defendants' liability under this contract when they purchased the defective medication.

96. Defendants breached express warranties about the defective Zantac and its qualities because Defendants' statements about the defective Zantac were false and the defective Zantac does not conform to Defendants' affirmations and promises described above.

97. Plaintiff and each of the members of the Class and New York Subclass would not have purchased the defective Zantac had they known the true nature of the defective Zantac's composition, specifically that Zantac contained elevated levels of NDMA.

COUNT III
Breach of Implied Warranties
(On Behalf of The Nationwide Class and the New York Subclass)

98. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

99. This claim is brought against all Defendants by Plaintiff on behalf of himself, the Nationwide Class, and the New York Subclass.

100. Under the New York Uniform Commercial Code, a warranty of merchantability is implied in every contract for the sale of goods. A contract for the sale of goods need not be written but "may be made in any manner sufficient to show agreement, including conduct by both parties which recognizes the existence of such a contract." N.Y. UCC § 2-204. Furthermore, the New York UCC does not require privity between Plaintiff and Defendants.

101. An implied warranty of merchantability is breached when the good or product at issue is defective or not fit for the ordinary purpose for which it is intended.

102. The Zantac manufactured and distributed by Defendants is and was defective because it exposes persons who take the drug to high levels of the carcinogen NDMA. Thus, Zantac

is defective and not fit for the ordinary purpose for which it is intended.

103. At the time that Defendants sold and warranted Zantac, they knew that Zantac was defective and not fit for the ordinary purpose for which it is intended. Nonetheless, Defendants wrongfully and fraudulently concealed these material facts from Plaintiff, Class members, and the New York Subclass. Plaintiff and all of the Class members were therefore induced to purchase Zantac under false or fraudulent pretenses.

104. Because of Defendants' breach of implied warranty, Plaintiff, the Class members and Subclass members seek a full refund of the purchase price of all Zantac they purchased that was manufactured and distributed by Defendants.

105. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff, Class members, and Subclass members have been damaged and request all damages they are entitled to under the Uniform Commercial Code, as well as any other legal or equitable relief that the Court deems just and appropriate.

COUNT IV
Fraudulent Concealment
(On Behalf of The Nationwide Class and the New York Subclass)

106. Plaintiff incorporates by reference all preceding allegations as though fully set forth herein.

107. The Plaintiff brings this claim against all Defendants on behalf of himself and the Nationwide Class and the New York Subclass.

108. Defendants intentionally concealed that Zantac is defective and unsafe because it exposes consumers to high levels of NDMA.

109. Defendants affirmatively misrepresented to Plaintiff, and all of the Class members in advertising and other forms of communication, including standard and uniform material

provided with the drug's packaging, that Zantac had no significant defects and was safe to consume.

110. Defendants knew about the defect in Zantac when they made these representations.

111. Defendants had a duty to disclose that Zantac contains a fundamental defect as alleged herein, because the defect created a risk to consumers' health and Plaintiff and all of the Class members and relied on Defendants' material representations.

112. At all relevant times, Defendants held out Zantac to be free from defects and to be a "safe" drug for consumers. Defendants' touted the many benefits and advantages of Zantac, but failed to disclose important facts related to the defect. This made Defendants' other statements about Zantac deceptive.

113. Plaintiff Class members and Subclass members did not know of the defects in Zantac, and Defendants actively concealed the defect from them.

114. Plaintiff Class members and Subclass members reasonably relied upon Defendants' deception. They had no way of knowing that Defendants' representations were false, misleading, or incomplete. As consumers, Plaintiff and all Class members and Subclass members did not, and could not, unravel Defendants' deception on their own. Rather, Defendants intended to deceive Plaintiff and all Class members by concealing the true facts about Zantac exposing consumers to high levels of the carcinogen NDMA.

115. Defendants' false representations and omissions were material to consumers because they concerned a quality of Zantac—safety—that played a significant role in the value of Zantac to consumers.

116. Defendants had a duty to disclose the Zantac defect because Defendants knew that the defect was not known to or reasonably discoverable by Plaintiff, Class members and Subclass

members.

117. Plaintiff Class members and Subclass members were unaware of the omitted material facts referenced herein, and they would not have acted as they did if they had known of the concealed or suppressed facts, in that they would not have purchased Zantac and would have taken other affirmative steps in light of the information concealed from them.

118. Because of Defendants' concealment and suppression of facts, Plaintiff and all Class members and Subclass members sustained damage because they would not have purchased or consumed Zantac but for Defendants' actions.

119. Plaintiff and all Class members and Subclass members seek damages, attorneys' fees, court costs, and any other legal or equitable relief that the Court deems just and appropriate.

120. Defendants' acts were done wantonly, maliciously, oppressively, deliberately, with intent to defraud, and in reckless disregard of Plaintiff's Class members' and Subclass members' rights, in order to enrich themselves. Plaintiff and all Class members and Subclass members request an assessment of punitive damages in an amount sufficient to deter such conduct in the future.

COUNT V
Violation of New York General Business Law § 350
(On Behalf of the New York Subclass)

121. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

122. This claim is brought against all Defendants by Plaintiff on behalf of himself, and the New York Subclass.

123. New York's General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

124. Pursuant to said statute, false advertising is defined as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

125. Based on the foregoing, Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of § 350 of New York's General Business Law.

126. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

127. Defendants' false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

128. Defendants' false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

129. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiff and the New York Subclass have suffered and continue to suffer economic injury.

130. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained elevated levels of NDMA and is not safe for human consumption; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

131. On behalf of himself and members of the New York Subclass, Plaintiff seeks to recover actual damages or $500, whichever is greater, plus three times actual damages and reasonable attorney's fees.

COUNT VI
Fraud
(On Behalf of the Nationwide Class and New York Subclass)

132. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint.

133. This claim is brought against all Defendants by Plaintiff on behalf of himself, the Nationwide Class, and the New York Subclass.

134. As discussed above, Defendants provided Plaintiff and the Nationwide Class and New York Subclass members with materially false or misleading information about the Zantac manufactured by Defendants. Specifically, Defendants have marketed Zantac as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' Zantac medications contained elevated levels of NDMA.

135. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and the Nationwide Class and New York Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and the Nationwide Class and New York Subclass members to purchase defective Zantac.

136. Defendants knew that Zantac was contaminated with this harmful impurity, but continued to manufacture it nonetheless. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine." Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable." During that time, Plaintiff and the Nationwide Class and New York Subclass members were using the medication without knowing it contained dangerous levels of NDMA.

137. The fraudulent actions of Defendants caused damage to Plaintiff and the

Nationwide Class and New York Subclass members, who are entitled to damages and other legal and equitable relief as a result.

138. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

A. For an order certifying the Nationwide Class and the New York Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as the representative for the Nationwide Class and New York Subclass and Plaintiff's attorneys as Class Counsel;

B. For an order declaring the Defendants' conduct violates the statutes referenced herein;

C. For an order finding in favor of Plaintiff, the Nationwide Class, and the New York Subclass on all counts asserted herein;

D. For compensatory, statutory, and punitive damages in amounts to be determined by the Court and/or jury;

E. For prejudgment interest on all amounts awarded;

F. For an order of restitution and all other forms of equitable monetary relief;

G. For injunctive relief as pleaded or as the Court may deem proper; and

H. For an order awarding Plaintiff and the Nationwide Class and New York Subclass their reasonable attorneys' fees and expenses and costs of suit.

JURY DEMAND

Plaintiff hereby demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

Dated: November 19, 2019

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